

REMARKS

The Examiner has maintained the rejection of claims 1, 3, 10 and 11 under 35 USC 102(b) as being anticipated by U.S. 6,117,316 to Ritchart, et al. Claim 10 has been cancelled.

The Applicants have argued that the sample tissue in Ritchart, et al. is retained in the inner cutter 18 as it is withdrawn by friction and the inner walls of the cannula by suction pressure within the lumen 20. See column 7, lines 19-24.

The Applicants have also pointed out that Ritchart, et al. states that, "the high vacuum pressure applied through the inner cutter lumen 20 from the proximal port 50 functions to retain the tissue specimen in the lumen during the ensuing transport of the cutter and specimen to a suitable tissue receptacle." (Emphasis Added)

Thus, the severed tissue is not evacuated through the needle. In fact, Ritchart, et al. teaches away from the present invention in that the severed specimen exits through the distal port 26 into a medical waste receptacle oil-like, thereby preventing blood and other waste from either clogging lumens 20 or 31 or apertures 56 or traversing proximately through the cutter lumen and discharging with the tissue specimen into the specimen and receptacle. In column 1, lines 39-44.

The Applicants have submitted accordingly that the method taught by Ritchart, et al. does not include any

teachings of evacuating severed tissue from the needle by vacuum. Since this step is not taught, there can be no anticipation under 35 USC 102(b).

Further, the Applicants have argued that there is no inherent anticipation inasmuch as the device of Ritchart, et al. is meant to save tissue in a receptacle for later biopsy. Accordingly, there is no discharge of severed tissue through a lumen.

The Examiner on page 5 of the Office Action has responded to the Applicants arguments in stating that, "it is well established that a recitation with respect to the manner in which an apparatus is intended to be employed, i.e., a functional limitation, does not impose any structural limitation upon the claimed apparatus which differentiates it from a prior art reference disclosing the structural limitations of the claim." (Emphasis added) Citing In re Pearson, 191 USPQ 641 (CCPA 1974); In re Casey, 152 USPQ 235 (CCPA 1967); In re Otto, 136 USPQ 458 (CCPA 1963).

The Applicants respectfully wish to point out that claims 1 and 3 are method claims, accordingly, no apparatus is set forth.

The In re Pearson reference is inapplicable to the present invention. The Pearson invention relates to a composition and used to inhibit the formation "pops" and "unsound kernels" during the growth of a peanut crop. The Pearson invention also involves the use of calcium compounds to reduce the occurrence of pops and unsound

kernels. Inasmuch as the present invention is directed to a method the cited case with regard to anticipation of a composition is not applicable.

The method claims cited in In re Pearson as being inherent are rejected on the process of Pearson not the apparatus or composition.

Claims 1 and 3 rejected by the Examiner, as amended, are directed to a method of controlling a surgical cutting device utilizing steps which are repeated at a rate of between one step per minute and about 1000 steps per minute. Support for this amendment may be found in the original specification on page 7, lines 4-8, accordingly no new matter has been added.

Clearly, the process as set forth in the Ritchart, et al. reference provides for retaining a tissue specimen in a lumen 20 during ensuing transport of the cutter and specimen proximally to a suitable tissue receptacle and a tissue chamber 58, see columns 7, lines 10-15.

Clearly, this extraction of a sample and transport to a receptacle cannot be accomplished at rates between 1 per minute and a 1000 per minute as set forth in the amended claims of the present application. Accordingly, rejection of claims 1 and 3 under 35 USC 102(b) cannot be sustained on the basis of the Ritchart, et al.

Claim 11 is directed to an improvement to a surgical apparatus which includes a controller, as currently amended, for providing vacuum communication at a rate of

been about 1 to about 1000 per minute. Accordingly, the Pearson, et al. reference does not anticipate, nor does it suggest, or inherently teach the present invention.

In the Office Action, the Examiner has also relied on In re Casey, 152 USPQ 235 (CCPA 1967), which is directed to a taping machine in which the claims were rejected under 35 USC 103.

In view of the fact that the present rejection is based upon 35 USC 102, the Applicants submit that the In re Casey reference is not applicable in the case at hand.

Further, the Examiner has relied on In re Otto, 136 USPQ 458 (CCPA 1963). This matter involves a new article of manufacture for a core member for hair curlers.

In this case, the courts stated that the claims are directed to a particular device and a method for making the device and not to a method of curling hair wherein this particular device is used. The court also stated that this method is irrelevant with regard to claims reciting hair being wound around the core, insofar as the determination of whether the particular claims should be allowed or rejected.

This is on all fours with the case at hand in which claims 1 and 3 are directed to a method and not to the device or method of making the device. Accordingly, the Applicants submit that this reference is not applicable to the matter at hand.

The Examiner has also stated that where the prior art reference is inherently capable of performing the function described in the functional limitation, such functional limitation does not define the claimed apparatus over such prior art reference, regardless of whether the prior art reference explicitly discusses such capacity for performing the recited function, the Examiner citing In re Ludtke, 169 USPQ 583 (CCP 1971).

The Applicants submit that the claims 1 and 3 are not directed to an apparatus but rather to a method and accordingly the In re Ludtke reference is not relevant.

Assuming arguendo that the In re Ludtke reference is applicable to the case at hand, the apparatus of Ritchart, et al. cannot inherently function in a manner set forth in the method presently claimed.

That is, the Ritchart, et al. reference is directed to biopsy apparatus which functions to singularly take samples from tissue and deposit same in a remote receptacle. This device teaches a method that cannot inherently anticipate the present invention which includes a method of controlling a surgical cutting device at a rate of between one step per minute and about a 1000 steps per minute.

Accordingly, the Ritchart, et al. reference cannot inherently perform the method of the present invention.

Further, with regard to the improvement claim 11, Ritchart cannot inherently provide a controller which operates at a rate of between 1 communication to about 1000

communications of vacuum between a vacuum source and a needle lumen.

The Examiner has further stated that in addition, where there is reason to believe that such functional limitation may be an inherent characteristic, the prior art reference, the Applicant is required to prove that the subject matter as shown in the prior art reference do not possess the characteristic and relied upon. In re Spada, 15 USPQ 2d 1655 (Fed. Cir. 1990); In re King, 231 USPQ 136, 138 (Fed. Cir. 1986); In re Ludtke, 169 USPQ 566 (CCPA 1971). The Examiner has concluded that the vacuum source connected to the needle 16 and supplying a vacuum to the needle disposed by Ritchart, et al. is capable of aspirating severed tissue through the lumen of the needle.

While Ritchart, et al. may be capable of aspirating severed tissue through a lumen, there is no structure which functions either directly or in an inherent manner teaching the regulating of vacuum to a hollow needle at a rate of between one step per minute and about 1000 steps per minute as set forth in the amended claims. This is not a functional limitation of apparatus claims but rather a directly claimed method.

As to specific proof, the Applicants submit that the process and device of Ritchart, et al. requires taking a sample and manually transporting the sampling device and tissue to a separate receptacle and such operation cannot be done at rates up to 1000 times per minute.

Accordingly, the Applicants respectfully request the Examiner to withdraw the rejection of claims 1, 3 and 11 under 35 USC 102(b) as being anticipated by Ritchart, et al.

Claims 2 and 7-9 have been rejected by the Examiner under 35 USC 103(a) as being unpatentable over U.S. 6,017,316 to Ritchart, et al. in view of U.S. 5,685,320 to Zimmon, et al.

With regard to this rejection, the Examiner has stated that Ritchart, et al. discloses applying vacuum to the tissue to bring the tissue into the port and moving the blade to sever the tissue. However, the Examiner acknowledges that Ritchart, et al. fails to disclose regulating the vacuum applied to the tissue or disclose regulating the position of the blade to control the amount of tissue severed during blade movement.

Accordingly, the Examiner reaches to Zimmon, et al. for a teaching at the size of the biopsy sample can be changed based upon the amount of vacuum or suction in the area that opening that receives the sample. The Examiner concludes that it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method that is disclosed by Ritchart, et al. to include the steps of regulating the vacuum applied to the tissue and regulating the position of the blade to allow for more or less to be open to the tissue in order to modify the size of the biopsy sample as taught by Zimmon, et al.

In traverse of this rejection, the Applicants submit that while Zimmon, et al. teaches that the size of the biopsy sample is determined by a number of independently controllable factors, there is no teaching of a method which includes the evacuation of severed tissue through a lumen.

Also, importantly there is no suggestion or teaching whatsoever of taking such biopsies at the rate of one per minute to about a 1000 per minute as would be necessary to provide a basis for combining with the Ritchart, et al. reference in order to present a prima facie case of obviousness of claims 2 and 7-9.

Accordingly, the Applicants respectfully request the Examiner to withdraw the rejection of claims 2 and 7-9 under 35 USC 103(a) on the basis of the Ritchart, et al. and Zimmon, et al. references.

Claims 4 and 6 have been rejected by the Examiner under 35 USC 103(a) as being unpatentable over U.S. 6,017,316 to Ritchart, et al. in view of U.S. 6,120,462 to Hibner, et al.

In this rejection, the Examiner acknowledges that Ritchart, et al. fails to disclose regulating the speed of moment of the blade, but that Hibner, et al. teaches a biopsy device wherein the speed of the cutter is regulated and concludes that it would have been obvious to one having ordinary skill in the art at the time the invention was made to regulate the speed of the blade as disclosed by

Ritchart, et al. in order to maintain the speed of the blade in an optimal range while translating through tissue.

The present invention is directed to a method and apparatus for severing and evacuating tissue from the surgical cite at a repetition rate of between one and about a 1000 strokes per minute. This is accomplished through aspiration of severed tissue through a needle. Hibner, et al. further teaches away from the present invention with regard to repetition of the method steps in that as set forth in column 8, beginning at line 7, Hibner, et al. states "...the tissue extracted from the surgical patient is retrieved by the operator and/or by an assistant from tissue sampling surface 64". Thus the sample does not flow through the lumen as provided in accordance with the present invention and further the repetition rate is not suggested or taught.

Accordingly, the Applicants submit that the Examiner has not made a prima facie case for obviousness under 35 USC 103(a) of claims 4-6 on the basis of the Ritchart, et al. and Hibner, et al. reference.

Finally, the Examiner has rejected claim 5 under 35 USC 103(a) as being unpatentable over U.S. 6,017,316 to Ritchart, et al. in view of U.S. 5,685,322 to Zimmon, et al. and further in view of U.S. 6,120,462 to Hibner, et al.

The Applicants reassert the herein presented argument and traverse this rejection on the basis that none of the reference cited by the Examiner include the severing of tissue and the aspiration thereof through a lumen at the



rates set forth in the method of the present invention. Accordingly the combination of a blade and vacuum as set forth in the claims of the present application is not taught by any of the cited references nor is there any inherent teaching in view of the significant difference of operation in all the devices set forth in the referenced patents.

In view of the arguments hereinabove set forth and of the claims, it is submitted that each of the claims now in the application define patentable subject matter not anticipated by the art of record and not obvious to one skilled in this field who is aware of the references of record. Reconsideration and allowance are respectively requested.

Respectfully submitted,

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